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Amendment and Response to Final Office Action

Remarks begin on page 45 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1. (Withdrawn) An acetabular liner for hip replacement comprising:

(a) an internal concave surface adapted to receive the head of a femoral component;

(b) an external surface positioned on an opposing side of the liner from the internal concave surface;

(c) a sculpted surface generally defining at least part of a rim of the liner, said surface located between the internal concave surface and an external surface of the liner; and

(d) wherein the sculpted surface is defined at least in part by, given a desired angular position of the liner in a patient:

the impingement angle, at each of a plurality of radial locations around the rim, of at least one femoral component whose head is adapted to be received in the internal concave surface of the liner and which femoral component is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim;

said impingement angle measured relative to a reference line defined by structure of the liner; and

wherein the shape of the sculpted surface varies around the rim of the liner in a manner corresponding to the cross-sectional shape of the portion of the at least one femoral component that is in an impingement condition with the liner.

2. (Withdrawn) A liner according to claim 1, wherein the reference line is an axis of the liner.

3. (Withdrawn) A liner according to claim 2, wherein the axis of the liner is the center axis of the internal concave surface of the liner.

4. (Withdrawn) A liner according to claim 2, wherein the axis of the liner is an axis substantially perpendicular to the center axis of the internal concave surface of the liner.

5. (Withdrawn) A liner according to claim 2, wherein the axis of the liner is an axis defined by the external surface of the liner.

6. (Withdrawn) A liner according to claim 1, wherein one femoral component is employed to define said sculpted surface.

7. (Withdrawn) A liner according to claim 1, wherein a plurality of femoral components are employed to define said sculpted surface.

8 (Withdrawn) A liner according to claim 7, wherein the sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, an angle determined using a group of impingement angles corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal concave surface of the liner.

9. (Withdrawn) A liner according to claim 7, wherein the sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, a cross-sectional envelope, determined using a group of cross-sectional shapes corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal concave surface of the liner.

10. (Withdrawn) A liner according to claim 1 where, in cross section, at least part of the sculpted surface is a chamfer.

11. (Withdrawn) A liner according to claim 1 where, in cross section, at least part of the sculpted surface is a curve.

12. (Withdrawn) A liner according to claim 11, wherein the radius of curvature and center of curvature of the curve varies relative to the structure of the liner in order to optimize range of motion of a femoral component whose head is adapted to be received in the internal concave surface of the liner.

13. (Withdrawn) A liner according to claim 11, wherein the curve is convex.
14. (Withdrawn) A liner according to claim 11, wherein the curve is concave.
15. (Withdrawn) A liner according to claim 1, wherein the sculpted surface varies around the rim of the liner and is symmetric about a plane.
16. (Withdrawn) A liner according to claim 1, wherein the external surface of the liner is adapted to be received directly into the acetabulum of a patient.
17. (Withdrawn) A liner according to claim 16, wherein the external surface of the liner is adapted to be secured into the acetabulum of a patient with bone cement.
18. (Withdrawn) A liner according to claim 1, wherein the external surface of the liner is adapted to be received within an acetabular shell, and the acetabular shell is adapted to be received in the acetabulum of a patient.
19. (Withdrawn) A liner according to claim 1 wherein the distance across the opening of the internal concave surface is from about 22mm to about 36mm.

20. (Withdrawn) A liner according to claim 1 wherein the external surface of the liner is adapted to be received in an acetabular shell with an external diameter of about 40mm to about 80mm.

21. (Withdrawn) A liner according to claim 1 further including a locking surface for securing the liner in an acetabular shell.

22. (Withdrawn) A liner according to claim 21, wherein the locking surface comprises a serrated edge.

23. (Withdrawn) A liner according to claim 1 further including a shoulder on said liner.

24. (Withdrawn) A liner according to claim 1, wherein the center of the internal concave surface is offset from the center of a surface in which the liner is adapted to be received.

25. (Withdrawn) A liner according to claim 24, wherein the center of the internal concave surface is shifted laterally by up to about 10 mm.

26. (Withdrawn) A liner according to claim 24, wherein the center of the internal concave surface is shifted laterally by about 4 mm.

27. (Withdrawn) A liner according to claim 24, wherein the center of the internal concave surface is shifted medially by up to about 8 mm.

28. (Withdrawn) A liner according to claim 1, wherein the opening of the internal concave surface is anteverted.

29. (Withdrawn) A liner according to claim 28, wherein the center axis of the internal concave surface of the liner is anteverted up to about 45 degrees relative to the central axis of a surface in which the liner is adapted to be received.

30. (Withdrawn) A liner according to claim 28, wherein the center axis of the internal concave surface of the liner is anteverted about 20 degrees relative to the central axis of a surface in which the liner is adapted to be received.

31. (Withdrawn) A liner according to claim 1, where the center axis of the internal concave surface of the liner is oriented up to about 45 degrees relative to the central axis of a surface in which the liner is adapted to be received.

32. (Withdrawn) A liner according to claim 1, where the center axis of the internal concave surface of the liner is oriented about 20 degrees relative to the central axis of a surface in which the liner is adapted to be received.

33. (Withdrawn) A liner according to claim 1, wherein the liner is a constrained liner wherein the internal concave surface of the liner provides greater than 180° of coverage of the head of a femoral component adapted to be received in the internal concave surface of the liner.

34. (Withdrawn) A liner according to claim 1, wherein the liner further comprises a recessed radial segment which dips below 180° of coverage of the head of a femoral component adapted to be received in the internal concave surface of the liner.

35. (Withdrawn) A liner according to claim 34, wherein the sculpted surface of the rim of the recessed radial segment varies

- (a) in a manner corresponding to the cross-sectional shape of at least one femoral component in an impingement condition with the liner, and
- (b) based at least in part on the impingement angle,
 - at each of a plurality of radial locations along the radial segment,
 - of at least one femoral component whose head is adapted to be received in the internal concave surface of the liner and which is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim of said radial segment,
 - said impingement angle measured relative to a reference line defined by structure of the liner.

36. (Withdrawn) A liner according to claim 1, wherein the internal concave surface of the liner provides less than 180° of coverage of the head of a femoral component adapted to be received in the internal concave surface of the liner.

37. (Withdrawn) A liner according to claim 1, further comprising a surface located between the surface of the internal diameter in which the head of the femoral component articulates and the rim surface, which serves to reduce dislocation.

38. (Withdrawn) A liner according to claim 1, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by a computer simulation of a liner and a femoral component, wherein the computer simulates rotation of the femoral component within the liner to define a radial location on the rim of the liner where the femoral component impinges on the rim, and determines the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

39. (Withdrawn) A liner according to claim 1, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by manually rotating the femoral component within a liner to define a radial location on the rim of the liner where the femoral component impinges on the rim, and

determining the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

40. (Withdrawn) A liner according to claim 1, wherein the internal concave surface is an internal diameter.

41. (Withdrawn) A liner according to claim 1, wherein the internal concave surface is generally hemispherical.

42. (Withdrawn) A liner according to claim 1, wherein the internal concave surface is generally oval.

43. (Withdrawn) A liner according to claim 1, wherein the internal concave surface is generally elliptical.

44. (Withdrawn) A liner according to claim 1, wherein the internal concave surface is generally oblong.

45. (Withdrawn) An acetabular liner for hip replacement comprising:

(a) an internal diameter adapted to receive the head of a femoral component;

- (b) an external surface positioned on an opposing side of the liner from the internal diameter;
- (c) a sculpted surface generally defining at least part of a rim of the liner, said surface located between the internal diameter and an external surface of the liner; and
- (d) wherein the sculpted surface is defined at least in part by, given a desired angular position of the liner in a patient:

the impingement angle, at each of a plurality of radial locations around the rim, of at least one femoral component whose head is adapted to be received in the internal diameter of the liner and which femoral component is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim;

said impingement angle measured relative to a reference line defined by structure of the liner; and

wherein the shape of the sculpted surface varies around the rim of the liner in a manner corresponding to the cross-sectional shape of the portion of the at least one femoral component that is in an impingement condition with the liner.

46. (Withdrawn) A liner according to claim 45, wherein the reference line is an axis of the liner.

47. (Withdrawn) A liner according to claim 46, wherein the axis of the liner is the center axis of the internal diameter of the liner.

48. (Withdrawn) A liner according to claim 46, wherein an axis of the liner is the axis substantially perpendicular to the center axis of the internal diameter of the liner.

49. (Withdrawn) A liner according to claim 46, wherein the axis of the liner is an axis defined by the external surface of the liner.

50. (Withdrawn) A liner according to claim 45, wherein one femoral component is employed to define said sculpted surface.

51. (Withdrawn) A liner according to claim 45, wherein a plurality of femoral components are employed to define said sculpted surface.

52. (Withdrawn) A liner according to claim 51, wherein the sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, an angle determined using a group of impingement angles corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal diameter of the liner.

53. (Withdrawn) A liner according to claim 51, wherein the sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, a cross-sectional envelope determined using a group of cross-sectional shapes corresponding to a plurality of

femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal diameter of the liner.

54. (Withdrawn) A liner according to claim 45 where, in cross section, at least part of the sculpted surface is a chamfer.

55. (Withdrawn) A liner according to claim 45 where, in cross section, at least part of the sculpted surface is a curve.

56. (Withdrawn) A liner according to claim 55, wherein the radius of curvature and center of curvature of the curve varies relative to the structure of the liner in order to optimize range of motion of a femoral component whose head is adapted to be received in the internal diameter of the liner.

57. (Withdrawn) A liner according to claim 55, wherein the curve is convex.

58. (Withdrawn) A liner according to claim 55, wherein the curve is concave.

59. (Withdrawn) A liner according to claim 45, wherein the sculpted surface varies around the rim of the liner and is symmetric about a plane.

60. (Withdrawn) A liner according to claim 45, wherein the external surface of the liner is adapted to be received directly into the acetabulum of a patient.

61. (Withdrawn) A liner according to claim 60, wherein the external surface of the liner is adapted to be secured into the acetabulum of a patient with bone cement.

62. (Withdrawn) A liner according to claim 45, wherein the external surface of the liner is adapted to be received within an acetabular shell, and the acetabular shell is adapted to be received in the acetabulum of a patient.

63. (Withdrawn) A liner according to claim 45 wherein the internal diameter is from about 22mm to about 36mm.

64. (Withdrawn) A liner according to claim 45 wherein the external surface of the liner is adapted to be received in an acetabular shell with an external diameter of about 40mm to about 80mm.

65. (Withdrawn) A liner according to claim 45 further including a locking surface for securing the liner in an acetabular shell.

66. (Withdrawn) A liner according to claim 65, wherein the locking surface comprises a serrated edge.

67. (Withdrawn) A liner according to claim 45 further including a shoulder on said liner.

68. (Withdrawn) A liner according to claim 45, wherein the center of the internal diameter is offset from the center of a surface in which the liner is adapted to be received.

69. (Withdrawn) A liner according to claim 68, wherein the center of the internal diameter is shifted laterally by up to about 10 mm.

70. (Withdrawn) A liner according to claim 68, wherein the center of the internal diameter is shifted laterally by about 4 mm.

71. (Withdrawn) A liner according to claim 68, wherein the center of the internal diameter is shifted medially by up to about 8 mm.

72. (Withdrawn) A liner according to claim 45, wherein the opening of the internal diameter is anteverted.

73. (Withdrawn) A liner according to claim 72, wherein the center axis of the internal diameter of the liner is anteverted up to about 45 degrees relative to the central axis of a surface in which the liner is adapted to be received.

74. (Withdrawn) A liner according to claim 72, wherein the center axis of the internal diameter of the liner is anteverted about 20 degrees relative to the central axis of a surface in which the liner is adapted to be received.

75. (Withdrawn) A liner according to claim 45, where the center axis of the internal diameter of the liner is oriented up to about 45 degrees relative to the central axis of a surface in which the liner is adapted to be received.

76. (Withdrawn) A liner according to claim 45, where the center axis of the internal diameter of the liner is oriented about 20 degrees relative to the central axis of a surface in which the liner is adapted to be received.

77. (Withdrawn) A liner according to claim 45, wherein the liner is a constrained liner wherein the internal diameter of the liner provides greater than 180° of coverage of the head of a femoral component adapted to be received in the internal diameter of the liner.

78. (Withdrawn) A liner according to claim 45, wherein the liner further comprises a recessed radial segment which dips below 180° of coverage of the head of a femoral component adapted to be received in the internal diameter of the liner.

79. (Withdrawn) A liner according to claim 78, wherein the sculpted surface of the rim of the recessed radial segment varies

(a) in a manner corresponding to the cross-sectional shape of at least one femoral component in an impingement condition with the liner, and

(b) based at least in part on the impingement angle,
at each of a plurality of radial locations along the radial segment,
of at least one femoral component whose head is adapted to be received
in the internal diameter of the liner and which is disposed to permit the desired limit of range
of motion at a corresponding radial location on said rim of said radial segment,
said impingement angle measured relative to a reference line defined
by structure of the liner.

80. (Withdrawn) A liner according to claim 45, wherein the internal diameter of the liner provides less than 180° of coverage of the head of a femoral component adapted to be received in the internal diameter of the liner.

81. (Withdrawn) A liner according to claim 45, further comprising a cylindrical wall surface located between the surface of the internal diameter in which the head of the femoral component articulates and the rim surface, which serves to reduce dislocation.

82. (Withdrawn) A liner according to claim 45, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement

condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by a computer simulation of a liner and a femoral component, wherein the computer simulates rotation of the femoral component within the liner to define a radial location on the rim of the liner where the femoral component impinges on the rim, and determines the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

83. (Withdrawn) A liner according to claim 48, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by manually rotating the femoral component within a liner to define a radial location on the rim of the liner where the femoral component impinges on the rim, and determining the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

84. (Withdrawn) An acetabular liner for hip replacement comprising:

- (a) an internal diameter adapted to receive the head of a femoral component, wherein the internal diameter is from about 22mm to about 32mm and wherein the opening of the internal diameter is anteverted;
- (b) an external surface adapted to be received in the internal diameter of an acetabular shell;

(c) a chamfered surface generally defining at least part of a rim of the liner, said surface located between the internal diameter and an external surface of the liner; and

(d) wherein the chamfer angle of the chamfered surface is defined at least in part by, given a desired angular position of the liner in a patient:

the impingement angle, at each of a plurality of radial locations around the rim, of at least one femoral component whose head is adapted to be received in the internal diameter of the liner and which femoral component is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim;

said impingement angle measured relative to a reference line defined by structure of the liner; and

wherein the chamfered surface varies around the rim of the liner in a manner corresponding to the cross-sectional shape of the portion of the at least one femoral component in an impingement condition with the liner.

85. (Withdrawn) The liner according to claim 84, where the center axis of the internal diameter of the liner is anteverted up to about 45 degrees relative to the central axis of the shell.

86. (Withdrawn) The liner according to claim 84, where the center axis of the internal diameter of the liner is anteverted about 20 degrees relative to the central axis of the shell.

87. (Withdrawn) The liner according to claim 84, where the internal diameter is about 28 mm.

88. (Withdrawn) A liner according to claim 84, wherein the reference line is an axis of the liner.

89. (Withdrawn) A liner according to claim 88, wherein the axis of the liner is the center axis of the internal diameter of the liner.

90. (Withdrawn) A liner according to claim 88, wherein the axis of the liner is an axis substantially perpendicular to the center axis of the internal diameter of the liner.

91. (Withdrawn) A liner according to claim 84, wherein a plurality of femoral components are employed to define said sculpted surface.

92. (Withdrawn) A liner according to claim 91, wherein the sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, an angle determined using a group of impingement angles corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal diameter of the liner.

93. (Withdrawn) A liner according to claim 91, wherein the sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, a cross-sectional envelope determined using a group of cross-sectional shapes corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal diameter of the liner.

94. (Withdrawn) A liner according to claim 84, wherein the chamfer angle varies around the rim of the liner and is symmetric about a plane.

95. (Withdrawn) A liner according to claim 84 wherein the external surface of the liner is adapted to be received in an acetabular shell with an external diameter of about 40mm to about 80mm.

96. (Withdrawn) A liner according to claim 84 further including a locking surface for securing the liner in an acetabular shell.

97. (Withdrawn) A liner according to claim 96, wherein the locking surface comprises a serrated edge.

98. (Withdrawn) A liner according to claim 84, wherein the center of the internal diameter is shifted laterally by up to about 10 mm.

99. (Withdrawn) A liner according to claim 84, wherein the center of the internal diameter is shifted laterally by about 4 mm.

100. (Withdrawn) A liner according to claim 84, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by a computer simulation of a liner and a femoral component, wherein the computer simulates rotation of the femoral component within the liner to define a radial location on the rim of the liner where the femoral component impinges on the rim, and determines the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

101. (Withdrawn) A liner according to claim 84, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by manually rotating the femoral component within a liner to define a radial location on the rim of the liner where the femoral component impinges on the rim, and determining the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

102. (Currently Amended) A prosthetic device comprising:

(a) an acetabular shell comprising an internal concave surface adapted to receive a liner and an external surface adapted to be received in an acetabulum; and

(b) an acetabular liner having:

an internal concave surface adapted to receive the head of a femoral component;

an external surface positioned on an opposing side of the liner from the internal concave surface and adapted to be received in the internal concave surface of the acetabular shell; and

a rim located between the internal concave surface and the external surface of the liner, at least a portion of the rim comprising a variable angle chamfer.

~~a sculpted surface generally defining at least part of a rim of the liner, said surface located between the internal concave surface and an external surface of the liner;~~
~~and~~

~~wherein the sculpted surface is defined at least in part by, given a desired angular position of the liner in a patient:~~

~~the impingement angle, at each of a plurality of radial locations around the rim, of at least one femoral component whose head is adapted to be received in the internal concave surface of the liner and which femoral component is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim;~~

~~said impingement angle measured relative to a reference line defined by structure of the liner; and~~

~~wherein the shape of the sculpted surface varies around the rim of the liner in a manner corresponding to the cross sectional shape of the portion of the at least one femoral component that is in an impingement condition with the liner.~~

103. (Currently Amended) A device according to claim 107 ~~102~~, wherein the reference line of the liner is an axis of the liner.

104. (Original) A device according to claim 103, wherein the axis of the liner is the center axis of the internal concave surface of the liner.

105. (Original) A device according to claim 103, wherein the axis of the liner is an axis substantially perpendicular to the center axis of the internal concave surface of the liner.

106. (Original) A device according to claim 103, wherein the axis of the liner is an axis defined by the external surface of the liner.

107. (Currently Amended) A device according to claim 102, wherein the variable angle chamfer varies according to angles measured at a plurality of radial locations around the rim relative to a reference line defined by structure of the liner. one femoral component is employed to define said sculpted surface of the liner.

108. (Currently Amended) A device according to claim 107 or 102, wherein the angles are impingement angles of a femoral component that includes a head adapted to be received in the internal concave surface of the liner and is disposed to permit the desired limit range of motion at a corresponding radial location on the rim. a plurality of femoral components are employed to define said sculpted surface of the liner.

109. (Currently Amended) A device according to claim 108, wherein the angles are sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, an angle determined using a group of impingement angles corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal concave surface of the liner.

110. (Currently Amended) A device according to claim 108, wherein the shape of the variable angle chamfer varies according to the cross-sectional shape of a portion of the femoral component that is in an impingement condition with the liner. sculpted surface is defined at least in part by, at each of a plurality of locations around the rim, a cross-sectional envelope determined using a group of cross-sectional shapes corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal concave surface of the liner.

111. (Withdrawn) A device according to claim 102 where, in cross section, at least part of the sculpted surface is a chamfer.

112. (Withdrawn) A device according to claim 102 where, in cross section, at least part of the sculpted surface is a curve.

113. (Withdrawn) A device according to claim 112, wherein the radius of curvature and center of curvature of the curve varies relative to the structure of the liner in order to optimize range of motion of a femoral component whose head is adapted to be received in the internal concave surface of the liner.

114. (Withdrawn) A device according to claim 112, wherein the curve is convex.

115. (Withdrawn) A device according to claim 112, wherein the curve is concave.

116. (Currently Amended) A device according to claim 102, wherein the variable angle chamfer sculpted surface varies around the rim of the liner and is symmetric about a plane.

117. (Currently Amended) A device according to claim 102 wherein the distance across the opening of the internal concave surface of the liner is from about 22mm to about 36mm.

118. (Original) A device according to claim 102 wherein the external surface of the liner is adapted to be received in an acetabular shell with an external diameter of about 40mm to about 80mm.

119. (Original) A device according to claim 102 wherein the liner further includes a locking surface for securing the liner in the acetabular shell.

120. (Original) A device according to claim 119, wherein the locking surface comprises a serrated edge.

121. (Currently Amended) A device according to claim 102 further including a shoulder on said the liner.

122. (Original) A device according to claim 102, wherein the center of the liner internal concave surface is offset from the center of the shell.

123. (Original) A device according to claim 122, wherein the center of the liner internal concave surface is shifted laterally by up to about 10 mm.

124. (Original) A device according to claim 122, wherein the center of the liner internal concave surface is shifted laterally by about 4 mm.

125. (Original) A device according to claim 122, wherein the center of the liner internal concave surface is shifted medially by up to about 8 mm.

126. (Original) A device according to claim 102, wherein the opening of the liner internal concave surface is anteverted.

127. (Currently Amended) A device according to claim 126, wherein the center axis of the liner internal concave surface ~~of the liner~~ is anteverted up to about 45 degrees relative to the central axis of the shell.

128. (Currently Amended) A device according to claim 126, wherein the center axis of the liner internal concave surface ~~of the liner~~ is anteverted about 20 degrees relative to the central axis of the shell.

129. (Currently Amended) A device according to claim 102, where the center axis of the liner internal concave surface ~~of the liner~~ is oriented up to about 45 degrees relative to the central axis of the shell.

130. (Currently Amended) A device according to claim 102, where the center axis of the liner internal concave surface ~~of the liner~~ is oriented about 20 degrees relative to the central axis of the shell.

131. (Withdrawn) A device according to claim 102, wherein the liner is a constrained liner wherein the internal concave surface of the liner provides greater than 180° of coverage of the head of a femoral component adapted to be received in the internal concave surface of the liner.

132. (Withdrawn) A device according to claim 102, wherein the liner further comprises a recessed radial segment which dips below 180° of coverage of the head of a femoral component adapted to be received in the liner internal concave surface of the liner.

133. (Withdrawn) A device according to claim 132, wherein the sculpted surface of the rim of the recessed radial segment varies

(a) in a manner corresponding to the cross-sectional shape of at least one femoral component in an impingement condition with the liner, and

(b) based at least in part on the impingement angle,
at each of a plurality of radial locations along the radial segment,
of at least one femoral component whose head is adapted to be received
in the internal concave surface of the liner and which is disposed to permit the desired limit
of range of motion at a corresponding radial location on said rim of said radial segment
said impingement angle measured relative to a reference line defined
by structure of the liner.

134. (Withdrawn) A device according to claim 102, wherein the internal concave surface of the liner provides less than 180° of coverage of the head of a femoral component adapted to be received in the internal concave surface of the liner.

135. (Currently Amended) A device according to claim 102, further comprising a surface located between the liner internal concave surface of the internal diameter in which the head of the femoral component articulates and the rim surface, which serves to reduce dislocation of a femoral component received within the liner.

136. (Withdrawn) A device according to claim 102, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by a computer simulation of a liner and a femoral component, wherein the computer simulates rotation of the femoral component within the liner to define a radial location on the rim of the liner where the femoral component impinges on the rim, and determines the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

137. (Withdrawn) A device according to claim 102, wherein the impingement angle and cross-sectional shape of the portion of a femoral component that is in an impingement condition with the liner, at each of a plurality of radial locations around the rim of the liner, is specified by manually rotating the femoral component within a liner to define

a radial location on the rim of the liner where the femoral component impinges on the rim, and determining the impingement angle and cross-sectional shape of the femoral component on the rim at that radial location.

138. (Original) A device according to claim 102, wherein the liner internal concave surface is an internal diameter.

139. (Original) A device according to claim 102, wherein the liner internal concave surface is generally hemispherical.

140. (Withdrawn) A device according to claim 102, wherein the liner internal concave surface is generally oval.

141. (Withdrawn) A device according to claim 102, wherein the liner internal concave surface is generally elliptical.

142. (Withdrawn) A device according to claim 102, wherein the liner internal concave surface is generally oblong.

143. (Original) A device according to claim 102, further comprising a femoral component comprising a head, neck and stem, wherein the head is adapted to articulate within the internal concave surface of the liner.

144. (Withdrawn) A method of making an acetabular liner with a variable rim surface geometry comprising:

- (a) providing an acetabular liner comprising
 - an internal concave surface adapted to receive the head of a femoral component,
 - an external surface positioned on an opposing side of the liner from the internal concave surface, and
 - a surface generally defining at least a part of a rim of the liner, said surface located between the internal concave surface and an external surface of the liner;
- (b) rotating a femoral component in the acetabular liner to define a radial location on the rim of the liner where the femoral component impinges on the rim and noting that radial location;
- (c) defining the impingement angle of the femoral component on the rim at this radial location and noting that impingement angle;
- (d) defining the location and desired shape of a cross-sectional rim segment at that impingement angle and radial location, based at least in part on the cross-sectional shape of the portion of the femoral component that is in an impingement condition with the liner, and noting that location and desired shape of the cross sectional rim segment;
- (e) rotating the femoral component in the acetabular liner to define a separate radial location on the rim where the femoral component impinges on the rim and noting that radial location;

(f) repeating (c)-(e) as desired; and
(g) forming the liner with a variable geometry rim surface using the data obtained in steps (b)-(f), whereby the shape of the liner rim varies at a plurality of radial locations in a manner corresponding to the cross-sectional shape of the portion of the femoral component that is in an impingement condition with the liner.

145. (Withdrawn) The method of claim 144 further comprising forming the liner with a variable geometry rim surface by extrapolating based on the data obtained in steps (b)-(f).

146. (Withdrawn) The method of claim 144 further comprising forming the liner with a variable geometry rim surface by interpolating based on the data obtained in steps (b)-(f).

147. (Withdrawn) The method of claim 144 wherein the rotation of the femoral component within the internal concave surface of the liner is relative to an anatomically relevant axis.

148. (Withdrawn) The method of claim 147, wherein the anatomically relevant axis is an axis running approximately through the center of rotation of a femoral component articulating within the internal concave surface of the liner, said axis oriented in a plane

substantially parallel to a plane of the body selected from the group consisting of the transverse, coronal, and saggital planes of the body.

149. (Withdrawn) The method of claim 144 wherein step (f) further comprises repeating steps (c) through (e) in desired angular increments.

150. (Withdrawn) The method of claim 149 wherein steps (c) through (e) are repeated in increments of about fifteen degrees.

151. (Withdrawn) The method of claim 144 wherein one femoral component is employed to define said rim surface geometry.

152. (Withdrawn) The method of claim 144 wherein a plurality of femoral components are employed to define said rim surface geometry.

153. (Withdrawn) The method of claim 152, wherein the rim surface geometry is defined at least in part by, at each of a plurality of locations around the rim, an angle determined using a group of impingement angles corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal concave surface of the liner.

154. (Withdrawn) The method of claim 152, wherein the rim surface geometry is defined at least in part by, at each of a plurality of locations around the rim, a cross-sectional envelope determined using a group of cross-sectional shapes corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are adapted to be received in the internal concave surface of the liner.

155. (Withdrawn) A method of making an acetabular liner with a variable geometry rim surface comprising:

- (a) in a computer containing at least a processing functionality, rendering functionality, and storage functionality,
simulating a femoral component and an acetabular component,
the acetabular component comprising a liner having an internal concave surface adapted to receive the head of a femoral component,
an external surface positioned on an opposing side of the liner from the internal concave surface, and
a surface generally defining at least a part of a rim of the liner, said surface located between the internal concave surface and an external surface of the liner;
- (b) in the computer, rotating a femoral component in the acetabular liner to define a radial location on the rim of the liner where the femoral component impinges on the rim and noting that radial location;
- (c) defining the impingement angle of the femoral component on the rim at this radial location and noting that impingement angle;

- (d) defining the location and desired shape of a cross-sectional rim segment at that impingement angle and radial location, based at least in part on the cross-sectional shape of the portion of the femoral component that is in an impingement condition with the liner, and noting that location and desired shape of the cross sectional rim segment;
- (e) in the computer, rotating the femoral component in the acetabular liner to define a separate radial location on the rim where the femoral component impinges on the rim and noting that radial location;
- (f) repeating (c)-(e) as desired; and
- (g) forming the liner with a variable geometry rim surface using the data obtained in steps (b)-(f), whereby the shape of the liner rim varies at a plurality of radial locations in a manner corresponding to the cross-sectional shape of the portion of the femoral component that is in an impingement condition with the liner.

156. (Withdrawn) The method of claim 155 further comprising forming the liner with a variable geometry rim surface by extrapolating based on the data obtained in steps (b)-(f).

157. (Withdrawn) The method of claim 155 further comprising forming the liner with a variable geometry rim surface by interpolating based on the data obtained in steps (b)-(f).

158. (Withdrawn) The method of claim 156 wherein the computer extrapolates based on the data obtained in steps (b)-(f).

159. (Withdrawn) The method of claim 157 wherein the computer interpolates based on the data obtained in steps (b)-(f).

160. (Withdrawn) The method of claim 155, wherein steps (b)-(f) are performed with a computer.

161. (Withdrawn) The method of claim 155 wherein, based on the data obtained in steps (b)-(f), the computer produces a set of specifications for forming a liner with a variable geometry rim surface.

162. (Withdrawn) The method of claim 155 wherein the rotation of the femoral component within the internal concave surface of the liner is relative to an anatomically relevant axis.

163. (Withdrawn) The method of claim 162, wherein the anatomically relevant axis is an axis running approximately through the center of rotation of a femoral component articulating within the internal concave surface of the liner, said axis oriented in a plane substantially parallel to a plane of the body selected from the group consisting of the transverse, coronal, and saggital planes of the body.

164. (Withdrawn) The method of claim 155 wherein step (f) further comprises repeating steps (c) through (e) in desired angular increments.

165. (Withdrawn) The method of claim 164 wherein steps (c) through (e) are repeated in increments of about fifteen degrees.

166. (Withdrawn) The method of claim 155 wherein one femoral component is employed to define said rim surface geometry.

167. (Withdrawn) The method of claim 155 wherein a plurality of femoral components are employed to define said rim surface geometry.

168. (Withdrawn) The method of claim 167, wherein the rim surface geometry is defined at least in part by, at each of a plurality of locations around the rim, an impingement angle determined using a group of angles corresponding to a plurality of femoral components in an impingement condition with the liner whose heads are received in the internal concave surface of the liner.

169. (Withdrawn) The method of claim 167, wherein the rim surface geometry is defined at least in part by, at each of a plurality of locations around the rim, a cross-sectional envelope determined using a group of cross-sectional shapes corresponding to a plurality of

femoral components in an impingement condition with the liner whose heads are received in the internal concave surface of the liner.

170. (Withdrawn) A method of replacing a hip joint in a patient comprising

(a) providing an acetabular liner having:

an internal concave surface adapted to receive the head of a femoral component;

an external surface positioned on an opposing side of the liner from the internal concave surface and adapted to be received directly in the acetabulum of a patient;

a sculpted surface generally defining at least part of a rim of the liner, said surface located between the internal concave surface and an external surface of the liner; and

wherein the sculpted surface is defined at least in part by, given a desired angular position of the liner in a patient:

the impingement angle, at each of a plurality of radial locations around the rim, of at least one femoral component whose head is adapted to be received in the internal concave surface of the liner and which femoral component is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim;

said impingement angle measured relative to a reference line defined by structure of the liner; and

wherein the shape of the sculpted surface varies around the rim of the liner in a manner corresponding to the cross-sectional shape of the portion of the at least one femoral component that is in an impingement condition with the liner.

- (b) surgically implanting and securing the liner within the acetabulum of a patient;
- (c) providing a femoral component, comprising a head, neck and a stem, wherein the head is adapted to articulate within the internal concave surface of the liner;
- (d) surgically implanting the stem of the femoral component into the femur of a patient; and
- (e) installing the head of the femoral component into the internal concave surface of the liner.

171. (Withdrawn) A method according to claim 170, wherein the liner is secured within the acetabulum with bone cement.

172. (Withdrawn) A method according to claim 170, wherein the liner is secured within the acetabulum with an integral bone in-growth surface.

173. (Withdrawn) A method according to claim 172, wherein the bone in-growth surface comprises a textured matrix incorporated into the material forming the external surface of the liner.

174. (Withdrawn) A method according to claim 173, wherein the textured matrix comprises a porous material.

175. (Withdrawn) A method according to 172, wherein the integral bone in-growth surface comprises a roughened surface comprising at least part of the external surface of the liner.

176. (Withdrawn) A method according to claim 170, wherein the liner is mechanically secured within the acetabulum of a patient.

177. (Withdrawn) A method according to claim 176, wherein the liner is mechanically secured in within the acetabulum of a patient with screw threads integral to the external surface of the liner.

178. (Withdrawn) A method according to claim 176, wherein the liner is mechanically secured within the acetabulum with bone screws.

179. (Withdrawn) A method of replacing a hip joint in a patient comprising:

(a) providing an acetabular liner having:

an internal concave surface adapted to receive the head of a femoral component;

an external surface positioned on an opposing side of the liner from the internal concave surface and adapted to be received in the internal concave surface of an acetabular shell;

a sculpted surface generally defining at least part of a rim of the liner, said surface located between the internal concave surface and an external surface of the liner; and

wherein the sculpted surface is defined at least in part by, given a desired angular position of the liner in a patient:

the impingement angle, at each of a plurality of radial locations around the rim, of at least one femoral component whose head is adapted to be received in the internal concave surface of the liner and which femoral component is disposed to permit the desired limit of range of motion at a corresponding radial location on said rim;

said impingement angle measured relative to a reference line defined by structure of the liner; and

wherein the shape of the sculpted surface varies around the rim of the liner in a manner corresponding to the cross-sectional shape of the portion of the at least one femoral component that is in an impingement condition with the liner.

(b) providing an acetabular shell comprising an internal concave surface adapted to receive the liner and an external surface adapted to be received in an acetabulum;

(c) surgically implanting and securing the shell in the acetabulum of a patient;

(d) securing the liner in the internal concave surface of the shell;

- (e) providing a femoral component, comprising a head, neck and a stem, wherein the head is adapted to articulate within the internal concave surface of the liner;
- (f) surgically implanting the stem of the femoral component into the femur of a patient; and
- (g) installing the head of the femoral component into the internal concave surface of the liner.

180. (Withdrawn) A method according to claim 179, wherein the liner is secured in the internal concave surface of the shell with a locking surface.

181. (Withdrawn) A method according to claim 180, wherein the locking surface comprises a serrated edge.

REMARKS

Assignee and the undersigned attorney thank Examiner Barrett for his review of this patent application. Claims 1-101, 111-115, 131-134, 136, 137, 140-142, and 144-181 have been withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected species. Claims 102-110, 116-130, 135, 138, 139, and 143 are pending for examination.

Use of *Harkess* as a Reference and the Declaration of Brian McKinnon

In the Office Action, claims 102 and 116 were rejected under § 102(a) as anticipated by Variations in Design Anteverted Acetabular Liners in THR by Harkess et al. ("Harkess"). Prior to this Office Action, the Examiner did not consider *Harkess* because Assignee submitted an undated copy of *Harkess*. In response, the undersigned counsel located an abstract for *Harkess* available on the Internet indicating that *Harkess* was presented at the 67th Annual Meeting of the American Academy of Orthopaedic Surgeons on March 15-19, 2000. The undersigned counsel re-submitted *Harkess*, along with the abstract printed from the Internet prior to this Office Action. The date of presentation of *Harkess* is after March 14, 2000, which is the filing date of the provisional patent application to which the present patent application claims priority. Thus, Assignee submits that *Harkess* may not be cited as prior art in connection with the present application.

However, Assignee notes that the abstract printed from the Internet and re-submitted with *Harkess* indicates a date of last modification of February 17, 2000. Assignee does not believe this indicates that the complete *Harkess* paper was available to the public at this earlier date. Moreover, Assignee does not believe that this abstract alone would teach or

suggest the claimed subject matter. Nevertheless, Assignee submits a DECLARATION OF BRIAN MCKINNON UNDER 37 C.F.R. § 1.131 concurrently herewith that establishes a date of invention prior to February 1, 2000 for the invention defined by the claims of the present application. Because Applicant's date of invention predates February 17, 2000, it is clear that *Harkess* (both abstract and paper) is not a proper reference against the present application.

For the above reasons, Assignee respectfully submits that *Harkess* may not be cited as prior art in connection with the present application. Accordingly, the rejection of claims 102 and 116 under § 102(a) in view of *Harkess* should be withdrawn, and claims 102 and 116 should be allowed for this reason and for reasons described further below.

Claim Amendments

Claims 102, 103, 107-110, 116, 117, 121, 127-130, and 135 are amended above. Assignee respectfully requests that the Examiner enter these amendments and reconsider the pending claims in view of these amendments and the remarks below. Amended claim 102 recites:

A prosthetic device comprising:

(a) an acetabular shell comprising an internal concave surface adapted to receive a liner and an external surface adapted to be received in an acetabulum; and

(b) an acetabular liner having:

an internal concave surface adapted to receive the head of a femoral component;

an external surface positioned on an opposing side of the liner from the internal concave surface and adapted to be received in the internal concave surface of the acetabular shell; and

a rim located between the internal concave surface and the external surface of the liner, at least a portion of the rim comprising a variable angle chamfer.

Support for the amendment of claim 102 is found throughout the specification and drawings, particularly beginning with page 13, line 8 of the specification and the text that follows. Dependent claims 103, 107-110, 116, 117, 121, 127-130, and 135 are also amended above in view of the amendment to independent claim 102 or to correct other informalities, such as typographical errors.

None of the prior art references cited by the Examiner teach or suggest an acetabular liner with at least a portion of the rim comprising a variable angle chamfer, as recited in claim 102. Thus, the rejections of claim 102 under 35 U.S.C. §§ 102 and 103 should be withdrawn, and claim 102 should be allowed. Each of claims 103-110, 116-124, 126-130, 135, 138, 139, and 143 ultimately depends from independent claim 102. Inasmuch as claims 103-110, 116-124, 126-130, 135, 138, 139, and 143 depend from and thereby include the limitations of claim 102, claims 103-110, 116-124, 126-130, 135, 138, 139, and 143 should also be allowed, for at least such dependencies.

Previous Rejection of Claims 107-110 under 35 U.S.C. § 112

The Action rejected claims 107-110 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 107 and 108 are amended above. Assignee submits that the rejection of claims 107-110 under 35 U.S.C. § 112 should be withdrawn, and claims 107-110 should be allowed.

**Previous Rejections of Claims 102-106, 117-130, 135, 138, 139, and 143
under 35 U.S.C. §§ 102 and 103**

As noted above, claims 102-110, 116-130, 135, 138, 139, and 143 are now pending in the application. The Action rejects claims 102-106, 117-124, 126-130, 135, 138, 139, and 143 under 35 U.S.C. § 102(b). The Action also rejects claims 102, 122, and 125 under 35 U.S.C. § 103. More specifically:

- Claims 102-106, 135, 138, 139, and 143 were rejected under § 102(b) as anticipated by The Effects of Neck Geometry and Acetabular Design on the Motion to Impingement in Total Hip Replacement by Thornberry et al. ("Thornberry");
- Claims 102 and 117-124 were rejected under § 102(b) as anticipated by Reflection® Lateralized Liners by Smith & Nephew ("S&N");
- Claims 102 and 126-130 were rejected under § 102(b) as anticipated by U.S. Patent No. 5,507,824 to Lennox ("Lennox"); and
- Claims 102, 122, and 125 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,879,404 to Bateman et al. ("Bateman").

Amended claim 102 is reproduced above for the Examiner's reference. In previously rejecting claim 102, the Examiner did not consider that at least a portion of the rim of the acetabular liner comprises a variable angle chamfer. Each of the above references discloses an acetabular shell and an acetabular liner, as well as some additional, commonly employed structural parameters of acetabular liners, such as anteversion of 20 degrees relative to the acetabular shell or shifting of the central axis of the acetabular liner laterally or medially about 4 mm. However, these references, alone or in combination, fail to teach or suggest an acetabular liner with at least a portion of the rim comprising a variable angle chamfer, as recited in amended claim 102.

Thornberry

Thornberry shows several acetabular liners. Among the liners pictured in *Thornberry* are a liner with a small chamfer (circled in the middle figure at the bottom of the fourth page of the reference) and a liner with a wider chamfer (circled in the figure on the right at the bottom of the fourth page of the reference). However, the chamfer shown in each of these drawings is a constant angle chamfer, and nothing in *Thornberry* teaches or suggests a liner with a portion of the rim comprising a variable angle chamfer.

S&N

S&N discloses a series of lateralized acetabular liners. The liners shown include a constant angle chamfer around a portion of the liner rim. However, *S&N* does not teach or suggest an acetabular liner with at least a portion of the liner rim comprising a variable angle chamfer.

Lennox

Lennox describes various embodiments of an anteverted acetabular liner, but does not disclose or suggest an acetabular liner with a portion of the rim that is a chamfer. *See Fig. 4; cols. 7-8.* Furthermore, because *Lennox* does not disclose a liner with a chamfer, it certainly cannot teach or suggest a liner where at least a portion of the rim comprises a variable angle chamfer.

Bateman

As shown in Figs. 1-5 and described in column 5 of *Bateman*, this reference does not teach or suggest an acetabular liner with a chamfer. The only chamfer disclosed by *Bateman* is part of the acetabular shell or molded onto the acetabular shell or liner. Moreover, the

chamfer shown in the drawings has a constant angle with no variability. Accordingly, *Bateman* does not teach or suggest the subject matter recited in amended claim 102.

For the above reasons, the rejections of claim 102 under §§ 102 and 103 should be withdrawn, and claim 102 should be allowed. Each of claims 103-110, 116-124, 126-130, 135, 138, 139, and 143 ultimately depends from independent claim 102. Inasmuch as claims 103-110, 116-124, 126-130, 135, 138, 139, and 143 depend from and thereby include the limitations of claim 102, claims 103-110, 116-124, 126-130, 135, 138, 139, and 143 should also be allowed, for at least such dependencies.

CONCLUSION

The foregoing, along with the Request for Continued Examination, Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR 1.137(b), and DECLARATION OF BRIAN MCKINNON UNDER 37 C.F.R. § 1.131, is submitted as a full and complete response to the Final Office Action mailed December 2, 2003 and the Notice of Abandonment mailed June 15, 2004. Assignee submits that claims 102-110, 116-130, 135, 138, 139, and 143 are allowable for at least the reasons set forth above, and allowance of these claims is respectfully requested. The Commissioner is authorized to charge any additional fees that may be due for this Amendment and Response, or credit any overpayment, to Deposit Account No. 11-0855.

Respectfully submitted,



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